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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/475,822	06/07/1995	MARC ALIZON	3495.0010-24	4214

22852 7590 05/22/2002

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/22/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/475,822

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 1996.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status

1. This rejection is non-final. It is noted that this application was suspended pending the result of Interference 102,822, which interference was resolved in favor of the other party. Therefore, the Chang et al patent, cited below in the 102 rejections, is properly 102(e) art which cannot be rebutted due to res judicata.
2. Separately, Applicant is requested, in any response to this office action, to submit a copy of the original claims which were submitted for interference, in order to determine which claims, if any, should be cancelled under 37 CFR 1.663.

Double Patenting

3. Claims 17 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 08/308,218 in view of White et al (U.S. Patent 4,677,054).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to the identical products, the HIV ORF R, with the current claim 17 simply including reagents for the hybridization reaction including controls and claim 18 further teaching the use of labels. .

Claim 13 of copending application No. 08/308,218 teaches the HIV ORF-R sequence. The claim does not teach hybridization reagents or labels.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Claim 13 of copending application No. 08/308,218 because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 15 and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-22 of copending Application No. 08/202,239 in view of White et al (U.S. Patent 4,677,054).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to the identical products, the HIV ORF R, with the current claim 17 simply including reagents for the hybridization reaction including controls and claim 18 further teaching the use of labels. .

Claims 11-22 of copending Application No. 08/202,239 teaches the HIV ORF-Q , ORF-1, ORF-2, ORF-3, ORF-4 and ORF-5 sequence. The claims also teach the use of labels. The claim does not teach hybridization reagents.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of claims 11-22 of copending Application No. 08/202,239 because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 11, 13, 15 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

The claims utilize the open "having" language which permits the inclusion of additional elements. "Having" is interpreted as being of identical scope to "comprising".

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 4000 and 9000 are presented below.

```
Query: 4010 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4069
          |||
Sbjct: 4197 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4256
pol      856 I P Y N P Q S Q G V V E S M N K E L K K
```

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Query: 4070 ttataggacaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4129
          |||
Sbjct: 4257 ttataggccaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4316
pol      876 I I G Q V R D Q A E H L K T A V Q M A V
```

```
Query: 4130 tcatccacaatttttaaagaaaaannnnnnnnnnnnnnntacagtgcaggggaaagaatag 4189
          |||
Sbjct: 4317 tcatccacaatttttaaagaaaaggggggattgggggtacagtgcaggggaaagaatag 4376
pol      896 F I H N F K R K G G I G G Y S A G E R I
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Query: 4190 tagacataatagcaacagacatacaaaactaaagaattacaaaaacaaattacaaaaattc 4249
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|||||
Sbjct: 4377 tagacataatagcaacagacatacaaaactaaagaattacaaaaacaaattacaaaaattc 4436
pol 916 V D I I A T D I Q T K E L Q K Q I T K I

Query: 4250 aaaattttcgggtttattacagggacagcagaaaatccactttggaaaggaccagcaaagc 4309
|||||
Sbjct: 4437 aaaattttcgggtttattacagggacagcagagatccactttggaaaggaccagcaaagc 4496
pol 936 Q N F R V Y Y R D S R D P L W K G P A K

Query: 4310 tcctctggaaaggtgaaggggcagtagtaatacaagataatagtgcataaaagtagtgc 4369
|||||
Sbjct: 4497 tcctctggaaaggtgaaggggcagtagtaatacaagataatagtgcataaaagtagtgc 4556
pol 956 L L W K G E G A V V I Q D N S D I K V V

Query: 4370 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4429
|||||
Sbjct: 4557 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4616
pol 976 P R R K A K I I R D Y G K Q M A G D D C

Query: 4430 tggcaagtagacaggatgaggattagaacatggaaaagtttagtaaaacaccatattgtat 4489
|||||
Sbjct: 4617 tggcaagtagacaggatgaggattagaacatggaaaagtttagtaaaacaccatattgtat 4676
pol 996 V A S R Q D E D ^^^

Query: 4490 gtttcagggaaagctaggggatgggttttatagacatcactatgaaagccctcatccaaga 4549
|||||
Sbjct: 4677 gtttcagggaaagctaggggatgggttttatagacatcactatgaaagccctcatccaaga 4736

Query: 4550 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4609
|||||
Sbjct: 4737 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4796

Query: 4610 ggtctgcatacaggagaaagagactggcatctgggtcagggagtctccatagaatggagg 4669
|||||
Sbjct: 4797 ggtctgcatacaggagaaagagactggcatctgggtcagggagtctccatagaatggagg 4856

Query: 4670 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4729
|||||
Sbjct: 4857 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4916

Query: 4730 tactttgactgtttttcagactctgctataagaaaggccttattaggacacatagttagc 4789
|||||
Sbjct: 4917 tactttgactgtttttcagactctgctataagaaaggccttattaggacacatagttagc 4976

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Query: 4790 cctaggtgtgaatatcaagcaggacataacaaggtaggatctctacaataacttggcacta 4849
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Sbjct: 4977 cctaggtgtgaatatcaagcaggacataacaaggtaggatctctacaataacttggcacta 5036

Query: 4850 gcagcattaataacacacaaaaagataaagccacctttgcctagtgttacgaaactgaca 4909
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Sbjct: 5037 gcagcattaataacacacaaaaagataaagccacctttgcctagtgttacgaaactgaca 5096

Query: 4910 gaggatagatggaacaagccccagaagaccaagggccacagagggagccacacaatgaat 4969
|||||
Sbjct: 5097 gaggatagatggaacaagccccagaagaccaagggccacagagggagccacacaatgaat 5156

Query: 4970 ggacactagagcttttagaggagcttaagaatgaagctgtagacattttcctaggattt 5029
|||||
Sbjct: 5157 ggacactagagcttttagaggagcttaagaatgaanctgtagacattttcctaggattt 5216

Query: 5030 ggctccatggcttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5089
|||||
Sbjct: 5217 ggctccatggcttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5276

Query: 5090 aagccataataagaattctgcaacaactgctgtttatccattttcagaattgggtgtcga 5149
|||||
Sbjct: 5277 aagccataataagaattctgcaacaactgntgtttatcca-tttcagaattgggtgtcga 5335

Query: 5150 catagcagaataggcgttactcgacagaggagagcaagaaatggagccagtagatcctag 5209
|||||
Sbjct: 5336 catagcagaataggcgttactcaacagaggagagcaagaaatggagccagtagatcctag 5395

Query: 5210 actagagccctggaagcatccaggaagtcagcctaaaactgcttgtagcattgtctattg 5269
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Sbjct: 5396 actaganccctggaagcatccaggaagtcagcctaaaactgcttgtagcattgtctattg 5455

Query: 5270 taaaaagtgttgctttcattgccaagtttgtttcataacaaaagccttaggcattctccta 5329
|||||
Sbjct: 5456 taaaaagtgttgctttcattgccaagtttgtttcataacaaaagccttaggcattctccta 5515
orfQ 1 C Q V C F T T K A L G I S Y

Query: 5330 tggcaggaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5389
|||||
Sbjct: 5516 tggcannaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5575
orfQ 15 G X K K R R Q R R R P P Q G S Q T H Q V

Query: 5390 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaatagcaatagtagc 5449
|||||

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Sbjct: 5576 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaatagcaatagcagc 5635
orfQ 35 S L S K Q ^^^

Query: 5450 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5509
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Sbjct: 5636 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5695

Query: 5510 gaaaatattaagacaaaagaaaaatagacagggttaattgatagactaatagaaagagcaga 5569
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Sbjct: 5696 gaaaatattaagacaaaagaaaaatagacagggttaattgatagactaatagaaagagcaga 5755
env 1 K E Q

Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629
|||||
Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggaaat 5815
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcaccatgctccttgggatgttgatgatctgtagtgtctacagaaaaattgtgggtca 5689
|||||
Sbjct: 5816 ggggcaccatgctccttgggatattgatgatctgtagtgtctacagaaaaattgtgggtca 5875
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5749
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Sbjct: 5876 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5935
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagagggtacataatgttttgggccacacatgcctgtgtaccca 5809
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Sbjct: 5936 atgctaaagcatatgatacagagggtacataatgttttgggccacacatgcctgtgtaccca 5995
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaaccacagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 5869
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Sbjct: 5996 cagaccccaaccacagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 6055
env 84 T D P N P Q E V V L V N V T E N F N M W

Query: 5870 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 5929
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Sbjct: 6056 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 6115
env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtaaaattaacccactctgtgttagtttaaagtgcactgatttgaagaatg 5989
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Sbjct: 6116 agccatgtgtaaaattaacccactctgtgttagtttaaagtgcactgatttggggaatg 6175

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env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcgaggagaatgataatggagaaaggagagataaaaaactgctc 6053
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Sbjct: 6195 taataccaatagtagtagcgaggaaatgatgatggagaaaggagagataaaaaactgctc 6254
env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaagcataagaggtaagggtgcagaaagaatatgcannnnnnnataa 6113
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Sbjct: 6255 tttcaatatcagcacaagcataagaggtaagggtgcagaaagaatatgcatttttttataa 6314
env 171 F N I S T S I R G K V Q K E Y A F F Y K

Query: 6114 acttgatataataccaatagataatgatactaccagctatacggttgacaagttgtaacac 6173
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Sbjct: 6315 acttgatataataccaatagataatgatactaccagctatacggttgacaagttgtaacac 6374
env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctccagtcattacacaggcctgtccaaagggtatcctttgagccaattcccatacattattg 6233
|||||
Sbjct: 6375 ctccagtcattacacaggcctgtccaaagggtatcctttgagccaattcccatacattattg 6434
env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctggttttgcgattctaaaatgtaataataagacggttcaatggaacaggacc 6293
|||||
Sbjct: 6435 tgccccggctggttttgcgattctaaaatgtaataataagacggttcaatggaacaggacc 6494
env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6353
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Sbjct: 6495 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6554
env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgtttaaattggcagctctggcagaagaagaggtagtaattagatctgccaatttcac 6413
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Sbjct: 6555 actgctgttgaatggcagctctagcagaagaagaggtagtaattagatctgccaatttcac 6614
env 271 L L L N G S L A E E E V V I R S A N F T

Query: 6414 agacaatgctaaaaccataatagtacagctgaaccaatctgtagaaattaattgtacaag 6473
|||||
Sbjct: 6615 agacaatgctaaaaccataatagtacagctgaaccaatctgtagaaattaattgtacaag 6674
env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaatacaagaaaaagtatccgtatccagagaggaccagggagagcatttgt 6533
|||||

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Sbjct: 6675 acccaacaacaataacaagaaaaagtatccgtatccagaggggaccagggagagcatttgt 6734
env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6593
|||||
Sbjct: 6735 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6794
env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacactttaaaacagatagatagcaaattaagagaacaatttggaataataaaaac 6653
|||||
Sbjct: 6795 gaatgccactttaaaacagatagctagcaaattaagagaacaatttggaataataaaaac 6854
env 351 N A T L K Q I A S K L R E Q F G N N K T

Query: 6654 aataatctttaagcagtcctcaggaggggaccagaaattgtaacgcacagttttaattg 6713
|||||
Sbjct: 6855 aataatctttaagcaatcctcaggaggggaccagaaattgtaacgcacagttttaattg 6914
env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6773
|||||
Sbjct: 6915 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6974
env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttggagtactaaaggggtcaaataacactgaaggaagtgcacacatcacctcccatg 6833
|||||
Sbjct: 6975 tacttggagtactgaaggggtcaaataacactgaaggaagtgcacacatcacactcccatg 7034
env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 6893
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Sbjct: 7035 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 7094
env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtgagacaaattagatgttcatcaaataattacagggctgctattaacaagagatgg 6953
|||||
Sbjct: 7095 catcagcgagacaaattagatgttcatcaaataattacagggctgctattaacaagagatgg 7154
env 451 I S G Q I R C S S N I T G L L L T R D G

Query: 6954 tggtaatagcaacaatgagtcgagatcttcagacctggaggaggagatatgagggacaa 7013
|||||
Sbjct: 7155 tggtaataacaacaatgggtccgagatcttcagacctggaggaggagatatgagggacaa 7214
env 471 G N N N N G S E I F R P G G G D M R D N

Query: 7014 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7073
|||||

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Sbjct: 7215 ttggagaagtgaattatataataataaagtagtaaaaaattgaaccattaggagtagcacc 7274
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaaggcaaagagaagagtgggtgcagagagaaaaaagagcagtggggaataggagcttt 7133
|||||
Sbjct: 7275 caccaaggcaaagagaagagtgggtgcagagagaaaaaagagcagtggggaataggagcttt 7334
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttccttgggttcttgggagcagcaggaagcactatgggcgacgctcaatgacgctgac 7193
|||||
Sbjct: 7335 gttccttgggttcttgggagcagcaggaagcactatgggcgacggtcaatgacgctgac 7394
env 531 F L G F L G A A G S T M G A R S M T L T

Query: 7194 ggtacaggccagacaattattgtctggtatagtgacgagcagacaatttgctgagggc 7253
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Sbjct: 7395 ggtacaggccagacaattattgtctggtatagtgacgagcagacaatttgctgagggc 7454
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7313
|||||
Sbjct: 7455 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7514
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctggggatttggggttg 7373
|||||
Sbjct: 7515 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctgggnatttggggttg 7574
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7433
|||||
Sbjct: 7575 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7634
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggaacagatttgggaataacatgacctggatggagtgggacagagaaattaacaatta 7493
|||||
Sbjct: 7635 tctggaacagatttgggaataacatgacctggatggagtgggacagagaaattaacaatta 7694
env 631 L E Q I W N N M T W M E W D R E I N N Y

Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7553
|||||
Sbjct: 7695 cacaagcttaatacattccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7754
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7613
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Sbjct: 7755 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7814
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaattattcataatgatagtaggaggcttggtagggtttaagaatagt 7673
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Sbjct: 7815 gctgtggtatataaaaaattattcataatgatagtaggaggcttggtagggtttaagaatagt 7874
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtacttttctgtagtgaatagagtttaggcagggatattcaccattatcgtttca 7733
|||||

Sbjct: 7875 ttttgctgtacttttctatagtgaatagagtttaggcagggatattcaccattatcgtttca 7934
env 711 F A V L S I V N R V R Q G Y S P L S F Q

Query: 7734 gaccacacccaatcccgaggggacccgacaggcccgaaggaatagaagaagaaggtgg 7793
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Sbjct: 7935 gaccacacccaaccccgaggggacccgacaggcccgaaggaatagaagaagaaggtgg 7994
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 7853
|||||

Sbjct: 7995 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 8054
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatctgaggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 7913
|||||

Sbjct: 8055 cgatctgaggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 8114
env 771 D L R S L C L F S Y H R L R D L L L I V

Query: 7914 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtgga 7973
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Sbjct: 8115 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtgga 8174
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 tctcctacagtattggagtcaggagctaaagaatagtgtgttagcttgctcaatgccac 8033
|||||

Sbjct: 8175 tctcctacagtattggagtcaggaaactaaagaatagtgtgttagcttgctcaatgccac 8234
env 811 L L Q Y W S Q E L K N S A V S L L N A T

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|||

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env 831 A I A V A E G T D R V I E V V Q G A C R

Query: 8094 agctattcgccacatacctagaagaataagacaggggcttggaaggatttttgctataaga 8153
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Sbjct: 8295 agctattcgccacatacctagaagaataagacagggccttgaaaggattttgctataaga 8354
orfF 1 D R A W K G F C Y K
env 851 A I R H I P R R I R Q G L E R I L L ^^

Query: 8154 tgggtggcaagtgggtcaaaaagtagtggttggtggatggcctgctgtaagggaagaatga 8213
|||||
Sbjct: 8355 tgggtggcaagtgggtcaaaaagtagtggttggtggatggcctactgtaagggaagaatga 8414
orfF 11 M G G K W S K S S V V G W P T V R E R M

Query: 8214 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctagaaaaacatg 8273
|||||
Sbjct: 8415 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctgaaaaacatg 8474
orfF 31 R R A E P A A D G V G A A S R D L E K H

Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333
|||||
Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534
orfF 51 G A I T S S N T A A T N A A C A W L E A

Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393
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Sbjct: 8535 aagaggaggaggaggtgggttttccactcacacctcaggtacctttaagaccaatgactt 8594
orfF 71 Q E E E E V G F P L T P Q V P L R P M T

Query: 8394 acaaggcagctgtagatccttagccactttttaaaagaaaagggggactggaagggctaa 8453
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Sbjct: 8595 acaaggcagctgtagatccttagccactttttaaaagaaaagggggactggaagggctaa 8654
orfF 91 Y K A A V D L S H F L K E K G G L E G L

Query: 8454 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513
|||||
Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714
orfF 111 I H S Q R R Q D I L D L W I Y H T Q G Y

Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573
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Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774
orfF 131 F P D W Q N Y T P G P G V R Y P L T F G

Query: 8574 ggtgctacaagctagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633
|||||
Sbjct: 8775 ggtgctacaagctagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834
orfF 151 W C Y K L V P V E P D K V E E A N K G E

Query: 8634 acaccagcttgttacaccctgtgagcctgcatggaatggatgaccggagagagaagtgt 8693

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|||||
Sbjct: 8835 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccctgagagagaagtgt 8894
orfF 171 N T S L L H P V S L H G M D D P E R E V
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Query: 8694 tagagtggaggtttgacagccgcctagcatttcatcacatggcccgagagctgcatccgg 8753
|||||
Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcatcacgtggcccgagagctgcatccgg 8954
orfF 191 L E W R F D S R L A F H H V A R E L H P
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Query: 8754 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 8813
|||||
Sbjct: 8955 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 9014
orfF 211 E Y F K N C ^^^
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Query: 8814 cagggaggcgtggcctggcgaggactggggagtggcgagccctcagatcctgcatataag 8873
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Sbjct: 9015 cagggaggcgtggcctggcgaggactggggagtggcgagccctcagatgctgcatataa 9074
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Query: 8874 cagctgctttttgcctgtactgggtctctctggttagaccagatctgagcctgggagctc 8933
|||||
Sbjct: 9075 cagctgctttttgcctgtactgggtctctctggttagaccagatttgagcctgggagctc 9134
```

Score = 2796 bits (1454), Expect = 0.0
Identities = 1477/1489 (99%)
Strand = Plus / Plus

It is noted that with regard to, for example, the sequence region between nucleotides 4487 and 5086 claimed in claim 11, there are two nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 599 nucleotide sequence which is the first sequence of claim 1, two errors would represent approximately a 0.3% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

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With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 11, 13, 15 and 17 under 102 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 11, 13, 15 and 17 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

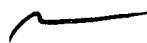
It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Chang because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White to detect HIV as taught by Chang since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER
Jeffrey Fredman
Primary Examiner
Art Unit 1637

May 15, 2002